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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,121	06/13/2000	JEFFREY SCHLOM	2026-4266US1	9401

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	**PAPER NUMBER**
1644	21

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/529,121	SCHLOM ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *20-45,49 and 50* is/are withdrawn from consideration.

5)☒ Claim(s) *6* is/are allowed.

6)☒ Claim(s) *1-5,7-19 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-50 are pending. Claims 20-45 and 49-50 have been withdrawn from consideration as being drawn to the non-elected invention.

Applicant's amendment filed 11-4-02, (Paper No. 18) and formal drawings (Paper No. 19) and Associate Power of Attorney (Paper No. 20), are acknowledged and have been entered.

The objections to the Abstract and to the drawings have been withdrawn, as has the 112 second paragraph rejection.

Election/Restrictions

Response to Arguments

Applicant traversal filed 11-4-02 (Paper No. 18), of the restriction requirement filed 12-18-01 (Paper 13), is on the grounds that the invention does have unity of because the invention does distinguish over the prior art. Applicant asserts in said traversal that the sequence YRSGENLNL does not anticipate claim 1 for the reasons discussed in Applicant's traversal of the art rejection applied in the office action mailed 6-4-02 (Paper No. 16) , and requests rejoinder of non-elected claims 20-45 and 49-50. This is not found persuasive for the reasons discussed below in response to Applicant's response to the art rejection of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Maintained Claims 1-5, 7-19 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide agonist of SEQ ID NO:1 consisting of the peptide SEQ ID NO:2, 3, 4 or 5, or a pharmaceutical composition thereof or a kit, wherein said sequences are an antagonist of the peptide consisting of SEQ ID NO:1's class I MHC HLA-A2 restricted T cell recognition, does not reasonably provide enablement for any other peptide agonist comprising any amino acid substitution of any non-anchor position(s) of SEQ ID NO:1 with increased immungenicity, or a kit thereof or a pharmaceutical composition thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant traverses the comprising language aspect of this rejection on the grounds that peptides of greater length than 8-10 amino acids may bind within the groove of MHC Class I molecules. However, the examiner notes that this is the exception rather than the rule because Janeway teaches only two examples of MHC Class I binding peptides that are longer than 8-10 amino acids long, among the thousands of MHC Class I binding peptides that have been identified. The instant specification does not exemplify a class I binding peptide greater than 8-10 amino acids, and in view of the dearth of such examples in the art, it would require undue experimentation for one of skill in the art to predict which additional sequences could be added and not negatively effect the binding of the residues of SEQ ID NO:1 to the MHC Class I protein.

Applicant traverses the aspect of the rejection that it would require undue experimentation for one of skill to predict which MHC non-anchor positions of SEQ ID NO:1 can be substituted given the variability of the positions of the non-anchor residues in peptides with respect to each MHC molecule, on the grounds that the experimentation needed to determine whether a given substitution would affect the agonistic activity of a peptide is minimal and well within the skill of an artisan. Applicant supports the traversal by an excerpt from the textbook by Male et al. which teaches that the effects of amino acid substitutions at each position of an immunogenic peptide on MHC antigen binding or on stimulation of functional T cells can be determined in order to classify an amino acid as making contacts with predominately MHC antigen, TCR, both or neither.

This is not found persuasive because said excerpt from Male does not address how to predict which positions contain non-anchor residues at all, and therefore, it is not clear how the Male excerpt substantiates Applicant's position that predicting which positions of SEQ ID NO:1 are non anchor would not require undue experimentation. In addition to not defining the non-anchor position of SEQ ID NO:1 the instant claims encompass any number of MHC molecules, and encompass any number of agonist activities.

Applicant further asserts that Ex parte Mark, 12 USPQ2d at 1907 would consider the claims enabled. However, unlike Mark, where substitutions of the cysteine residue that did not adversely impact the three-dimensional structure of the protein were considered enabling, the instant claims encompass substitutions that actually change the three dimensional structure to fit innumerable MHC molecules (including class I and class II proteins), wherein in the case of MHC Class I proteins, each MHC Class I protein requires that the peptide bound to it have a distinct 3 dimensional structure to fit the unique peptide binding pockets of each of said MHC class I proteins. In view of the breadth of these claims with respect to the three dimensional structure of the peptides encompassed by the instant claims, it would require undue experimentation for one of skill to practice the claimed invention. Though Applicant's arguments have been carefully considered they are not deemed persuasive and the rejection is maintained essentially for the reasons of record.

Maintained Claims 1-5, 7-19 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses the examiner's assertion in the instant rejection that only a partial structure of the agonist is recited since the anchor positions can be any amino acid, including naturally occurring amino acids, and also non naturally occurring amino acids, is factually inaccurate because the specification discloses on pages 5 and 33-34 that positions 2 and 9 are the primary anchor sites and position 1 is a secondary anchor site, and that the limitations of the claims do not allow for substitution of these positions. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner notes that said limitations are not recited in the instant claims, and further notes that the instant claims don't even recite that the peptide is a MHC Class I binding peptide, protein, never mind a specific MHC Class I binding peptide with a specific peptide binding motif comprising anchor and non-anchor positions.

Applicant also traverses the instant rejection with respect to the examiner's assertion in the instant rejection that since the peptide comprises a nonamer, said peptide can also encompass an indeterminate number and type of additional amino acids, in addition to the recited nonamer. The traversal is on the grounds that because the MPEP states that the term comprising is a term of art that leave the claim open for the inclusion of unspecified ingredients even in major amounts, and that the examiner has not met the burden of showing why a person skilled in the art would not recognize in Applicant's disclosure a description of the invention defined by the claims as required by MPEP 2163.04. However, though other unspecified ingredients may be encompassed by some claims reciting the term comprising, in the instant case there are no other ingredients except the peptide itself, and therefore there are no other ingredients. The instantly recited peptide does not meet the written description requirements because the number and type of additional amino acids incorporated by the peptide which would meet the functional limitations of the instant claims are not adequately described as outlined in the written description rejection of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Maintained Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnett, T., Goebel, S.J., Nothdurft, M.A. and Elting, J.J. Genomics 3 (1), 59-66 (1988) according to an NCBI blast search (of record, see restriction).

Applicant traverses the rejection on the grounds that claims 1 and 2 do not allow for substitution at anchor positions, the referenced sequence cannot anticipate said claims.

However, the examiner notes that said limitation that the claims do not allow for substitution at anchor positions is not recited in the instant claims. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further it is noted by the examiner that no single MHC molecule is recited in the claims, therefore it is not clear what the anchor positions are.

Applicant further contends that Applicant screened peptides consisting of the sequence of SEQ ID NO:1 with a single amino substitution at position number 5, an found that all substitutions resulted in reduced stimulation, and thus did not have an agonist effect. However it is noted by the examiner that the referenced peptide has a substitution at position #2 as well as position #5, and said peptide was not tested. Further it is noted that said claims do not recite what the agonistic activity is, what the restricting MHC molecule is, and has open language and therefore comprises peptides larger than 9 amino acids.

Conclusion

Claim 6 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
February 4, 2003

Patrick J. Nolan, Ph.D.,
Primary Patent Examiner